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REMARKS

Claims 1-65 are pending in the subject application. Applicants note that the Examiner has withdrawn claims 18-65 from further consideration. Applicants have hereinabove cancelled claim 4 without prejudice or disclaimer to their right to pursue the subject matter of this claim in a later-filed application. Applicants have also hereinabove amended claims 1-3 and 5-17. Support for the phrase "deletions, additions and substitutions thereof" in claim 2 may be found inter alia in the specification on page 31, line 16. The remaining amendments to the claims are for clarification only and do not present any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1-3 and 5-17 will be pending and under examination.

In view of the arguments and amendments set forth below, applicants maintain that the Examiner's objections and rejections have been overcome and respectfully request that the Examiner reconsider and withdraw same.

Election/Restriction

The Examiner stated that applicants' election with traverse of Group I, claims 1-17 in paper number 10 is acknowledged. The Examiner stated that the traversal is on the grounds that all groups are not independent and that "Groups I-XI are necessarily related." The Examiner stated that this was not found persuasive for the following reasons. The Examiner stated that Group I was decided to be independent from Groups VI-VII for the reasons given in the Restriction of paper no. 10, wherein it is stated in the MPEP 806.04 the claimed inventions of the Groups I and VI-VII

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are not capable of use together. The Examiner stated that Groups II-IV, VI-VII and VIII-XI were decided to be independent wherein again the claimed inventions are incapable of use together and under the MPEP 8006.04 are to be restricted as independent claims. The Examiner stated that Group V was determined to be independent from Groups II-IV and VIII-XI for the reasons set forth in paper no. 10 and wherein under MPEP 806.04 are to be restricted as independent claims wherein the Group V is incapable of use together with the methods of Groups II-IV and VIII-XI.

The Examiner stated that applicants argue that there are two criteria for a proper restriction requirement. The Examiner stated that the first criterion was established in paper no. 10 and reaffirmed as explained above. The Examiner stated that the second criterion requires a serious burden on the Examiner for searching. The Examiner stated that he established in paper no. 10 that the additional inventions would require additional searches since the search for one Group would not be inclusive of any other Group, and therefore a burden upon the Examiner. The Examiner concluded that the requirement is still deemed proper and is therefore made final.

In response, applicants respectfully traverse. Applicants note that claim 1, as amended, is directed to a single species, i.e. a regulatory peptide comprising SEQ ID NO:1. Withdrawn claims 18-30 are directed to methods of using the regulatory peptide of claim 1. Applicants maintain that claims 1-3 and 5-30 are related and therefore not "independent". Therefore, it would not be a burden on the Examiner to examine claims 1-3 and 5-17 with claims 18-30 in the subject application. Accordingly, applicants respectfully request that the Examiner reconsider and rejoin claims 18-30 such that claims 1-3 and 5-30 will be under examination.

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Claim Objections

The Examiner objected to claims 1-4, 7, 12 and 14 for the improper identification of a sequence, wherein each claim recites "SEQ ID:No...", however, the proper recitation should read "SEQ ID NO:".

The Examiner objected to claim 1 because the Examiner required that the term "A" be inserted before the term "regulatory."

The Examiner objected to claims 2 and 4 because the Examiner required the term "The" to identify the peptide being claimed.

The Examiner objected to claim 4 under 37 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner required applicants to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The Examiner stated that claim 4 does not further limit claim 3, wherein the terms "comprising" of claim 3 and "having" of claim 4 are considered open language, therefore, claim 4 is merely a non-limiting repeat of claim 3.

The Examiner stated that claims 5 and 6 cite "A". The Examiner suggested that the claims be amended to read as follows for claim 5, "The peptide according to claim 3, which is linear" and claim 6 should read as follows, "The peptide according to claim 3, which is cyclic".

The Examiner objected to claims 7 and 9-17 under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The

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Examiner required applicants to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. The Examiner stated that claims 7 and 9-10 recite a product and no tangible limitation, wherein the prophetic term "capable" does not lend limitation to the metes or bounds. The Examiner stated that therefore the claims are only to the peptide of the respective parent claims. The Examiner stated that claims 11-17 are merely intended use claims of the peptides of their respective parent claims and therefore lack any further limitation to the respective parent claims.

The Examiner objected to claims 7-17 for the use of the term "A" when referencing the peptides of previous claims. The Examiner stated that the term should be deleted and the term "The" inserted.

In response, applicants respectfully traverse the Examiner's above objection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have hereinabove canceled claim 4 without prejudice or disclaimer to their right to pursue this claim in a later-filed application.

In addition, without conceding the correctness thereof, applicants have hereinabove amended claims 1-3 and 5-17 to address the claim language objected to by the Examiner.

In view of the above remarks, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of objection.

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Claim Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-17 under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner rejected claim 1 because it is allegedly unclear if the peptide one of cell growth activity OR one cell differentiation activity OR if the peptide must have at least one of each combined. The Examiner stated that the use of the term "of" in the phrase "at least one [of] cell growth and cell differentiation activity" is unclear. The Examiner stated that claim 1 is also rejected for the indefinite use of the term "activity" wherein it is unclear what the definition and metes and bounds of the term are, i.e. cellular use of water is an activity that occurs during differentiation; thus, if the product promotes or induces differentiation then the term "activity" could be deleted to more clearly specify what is claimed in the invention. The Examiner rejected claim 1 for the improper Markush language wherein the language "having at least one of..." is vague and unclear. The Examiner also rejected claim 1 for vague language wherein it is unclear if SEQ ID NO:1 is the sequence for acetylcholinesterase or if SEQ ID NO:1 is the sequence for the regulatory peptide.

The Examiner rejected claim 2 for the indefinite recitation of "substantially" wherein the term is vague and offers no boundaries of the metes and bounds for the claimed regulatory peptide.

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The Examiner rejected claims 7 and 9-10 wherein the claims do not recite a limitation by the use of the indefinite term "capable" wherein the term "capable" is suggestive and prophetic by nature.

The Examiner rejected claim 8 for the indefinite recitation of the phrase, "which is any one of hematopoietic stem cell growth and differentiation regulatory peptide." The Examiner stated that the peptide can be a specific type of peptide, i.e. differentiation regulatory peptide; however, the claimed peptide cannot be a hematopoietic stem cell growth. The Examiner stated that the structure suggests the peptide is capable of being an activity. The Examiner stated that applicants should insert peptide after growth to better clarify that the claim is drawn to a "hematopoietic stem cell growth peptide."

The Examiner rejected claims 9 and 15 because it is unclear if applicants are claiming promotion of stem cell survival and either myeloid or megakaryocytic differentiation or stem cell survival and both myeloid and megakaryocytic differentiation.

The Examiner rejected claims 11-14 for depending from rejected claims.

In response, applicants respectfully traverse the Examiner's above rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have hereinabove canceled claim 4 without prejudice or disclaimer to their right to pursue this claim in a later-filed application.

In addition, without conceding the correctness thereof, applicants have hereinabove amended claims 1-3 and 5-17 to

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address the claim language objected to by the Examiner.

In view of the above remarks, applicants contend that claims 1-3 and 5-17 satisfy the requirements of 35 U.S.C. §112, second paragraph. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-17 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

The Examiner stated that this is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. §112, first paragraph. The Examiner directed applicants to the Guidelines for the examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement (cite omitted).

The Examiner stated that *Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The Examiner stated that the invention, for purposes of the "written description" inquiry, is *whatever is now claimed*."

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The Examiner stated that a review of the language of the claim indicates that these claims are drawn to a genus, i.e. the peptides comprising an amino acid sequence "derived" from the C-terminal region of the read-through variant of acetylcholinesterase as denoted by SEQ ID NO:1. The Examiner stated that a description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus(cite omitted). The Examiner stated that in *Regents of the University of California v. Eli Lilly*, the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The Examiner stated that the court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. The Examiner stated that at section B(1), the court states "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

The Examiner stated that there are no specifically indicated species of the claimed genus disclosed that are within the scope of the claimed genus, i.e. peptides comprising amino acid sequence substantially as denoted by SEQ ID NO:1. The Examiner stated that the disclosure of one or two species may provide an adequate written description of a genus when the species disclosed are representative of the genus. The Examiner stated that however, the present claim encompasses numerous species that

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are not further described. The Examiner stated that there is substantial variability among the numerously possible species.

The Examiner stated that one of skill in the art would not recognize from the disclosure that the applicants were in possession of the genus of peptides comprising amino acid sequence substantially as denoted by SEQ ID NO:1. The Examiner stated that the specification does not "clearly allow persons of ordinary skill in the art to recognize that they invented what is claimed" (citing Vas-Cath).

In response, applicants respectfully traverse the Examiner's above rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application have hereinabove canceled claim 4 without prejudice or disclaimer to their right to pursue this claim in a later-filed application.

In addition, without conceding the correctness thereof, applicants have hereinabove amended claims 1-3 and 5-17 to address the claim language objected to by the Examiner.

In view of the above remarks, applicants contend that claims 1-3 and 5-17 satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

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Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection and objection and earnestly solicit allowance of the now pending claims, i.e. claims 1-3 and 5-17, and rejoinder of claims 18-30.

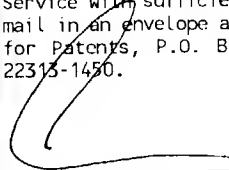
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. If any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


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4/5/02
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